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MYERS BIGEL SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			BAUSCH, SARAE L	
			ART UNIT	PAPER NUMBER
			1634	

DATE MAILED: 08/02/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/912,072

Applicant(s)

MOYER ET AL.

Examiner

Sarae Bausch

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 10, 11, 21-24, 27-30, 52, 63, 64 and 69-74 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3, 5-7, 21, 23, 24, 30, 63 and 69-74 is/are rejected.
- 7) ☒ Claim(s) 2, 4, 10, 11, 22, 27-29, 52, 64 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This action is written in response to applicant's correspondence submitted on 05/12/2006.
2. Currently, claims 1-7, 10-11, 21-24, 27-30, 52, 63-64, and 69-74 are under examination in the instant application. Claims 8-9, 12-20, 25-26, 31-51, 53-62 and 65-68 have been canceled. All the amendments and arguments have been thoroughly reviewed but were found insufficient to place the instantly examined claims in condition for allowance. Response to arguments follow. This action is **FINAL**.
3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Status

4. It is noted that newly added claims 70-74 do not comply with 37 CFR 1.121, as newly added claims do not require that the entire text be underlined. As stated MPEP714(c)(3) "When claim text in clean version is required. The text of all pending claims not being currently amended shall be presented in the claim listing in clean version, i.e., without any markings in the presentation of text. The presentation of a clean version of any claim having the status of "original," "withdrawn" or "previously presented" will constitute an assertion that it has not been changed relative to the immediate prior version, except to omit markings that may have been present in the immediate prior version of the claims of the status of "withdrawn" or "previously presented." Any claim added by amendment must be indicated with the status of "new" and presented in clean version, i.e., without any underlining.

Declaration

5. The declaration submitted under 37 CFR 1.132 filed on 05/12/2006 by James W. Moyer, is acknowledged, however is not found persuasive to overcome the maintained rejections and is addressed in the response to arguments sections below.

New Grounds of Rejections

Claim Rejections - 35 USC § 112-Second Paragraph

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 70-74 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "cultivar-linked" in claim 70-74 is a relative term which renders the claim indefinite. It is not clear what the "cultivar-linked" amplified polymorphic restriction fragments features are, the type of restriction fragments that occurs from "cultivar-linked" products, and what else the claimed fragment might comprise. Further, it is unclear what limitation of the amplified polymorphic restriction fragment is defined in the term "cultivar-linked". The term "cultivar-linked" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably appraised of the scope of the invention.

Claim Rejections - 35 USC § 112-New Matter

8. The following is a quotation of the first paragraph of 35 U.S.C. 112:

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The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 70-74 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Newly added claims 70-74 with the recitation of “cultivar-linked amplified polymorphic restriction fragments” is not supported in the specification and raises the issue of new matter. The specification teaches on pages 3, lines 20-24 amplified restriction fragments that are polymorphic between genotypes and in specific combinations correlate with cultivar identity. The specification teaches in example 2 optimization of AFLP analysis by obtaining optimal primer pairs by testing 64 primer pairs using AFLP (see page 24, lines 30-32) assert that the screening allowed for determination of primers that were appropriate to use with poinsettia (see page 24, lines 33-34), however the specification does not teach cultivar-linked amplified polymorphic restriction fragments. The specification does not provide a working example or a definition for an amplified polymorphic restriction fragment that is cultivar-linked. There is no support in the specification for the a fingerprint that comprises a collection of cultivar-linked amplified polymorphic restriction fragments and raises the issue of new matter.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3, 5-7, 21, 23-24, 63 and 69-74 rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al. (*HortScience*, 1997) in view of Loh et al. (*Annals of Botany*, 1999 84(2): 155-161), as defined by Dice (*Ecology*, 1945). It is noted that this rejection was previously presented in section 6 of the office action mailed 08/10/2005 and is applied to newly added claims 70-74 and reiterated below.

Ling et al. teaches a method of distinguishing genetic relationships and diversity between Poinsettia cultivars, including breeding family 'Freedom' (instant claim 5). The method utilizes RAPD analysis to distinguish the identities between Poinsettia cultivars in order to "alleviate some of the confusion of cultivar identity associated with morphological characteristics and

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multiple cultivar registrations” (p. 124, 1st-2nd column). Figure 3 displays the amplified restriction fragments generated by RAPD analysis and figure 1 demonstrates the cultivar relationships (cultivar linked amplified polymorphism restriction fragments) (claims 71-74). The collection of RAPD data, or database as require in claim 28, enables the computation of the displayed cultivar relationships both in Figure 1 and 2. Ling et al. teach that the RAPD markers can be used for identification of poinsettia cultivars and that the results indicate that RAPD can be used to determine the genetic relationships among cultivars and to estimate genetic diversity between cultivars (page 124, 1st full paragraph). Ling et al. does not teach the AFLP method steps to distinguish genetic relationship or diversity.

Loh et al. teach a method using an AFLP marker protocol to identify and study intra- and inter- specific variations in *Caladium bicolor* cultivars, an ornamental asexual plant. Loh et al. teach using AFLP to generate a fingerprint of each plant (page 151, paragraph bridging 1st and 2nd column) and determine the identity/diversity by calculating the genetic dissimilarly estimate (GDE) in all pair wise comparisons (page 159, *Data analysis*) (instant claims 63 and 69). Loh et al. teach digesting genomic DNA with EcoRI and Mse I (page 159, *AFLP analysis*) (instant claims 7, 24), which have tetranucleotide and hexanucleotide recognition sites (instant claims 6, 23). The genetic dissimilarity of *Caladium bicolor* is shown in table 3 and table 4, determining the diversity of the each cultivar of *Caladium bicolor* and *C. schomburgkii* (page 157 and 160) (instant claims 3 and 21). Dice defines the values or scores range from 0 to 1 where 0 indicates dissimilarity and 1 indicates similarity (pp. 298-99, bridging paragraph). Loh et al. also teach using AFLP revealed consistent diversity between *C. schomburgkii* and *C. bicolor* cultivars and between closely related taxa of *Caladium* (page 161, 1st column, 2nd full paragraph). Loh et al.

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et al. teach using AFLP markers is useful in differentiating and characterizing cultivars within a *Caladium* species (page 161, 1st column, last paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the method of identifying poinsettia cultivars by RAPDs marker taught by Ling et al. to include the AFLP marker assay as taught by Loh et al. One of ordinary skill in the art would have been motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Loh et al. because Loh et al. teaches of the advantages of using the AFLP procedure to analyze genetic relationships and diversity in ornamental plants in order to obtain reproducible and reliable results. The ordinary artisan would have had a reasonable expectation of success in using AFLP marker assay taught by Loh in the method taught by Ling et al. of Poinsettia cultivar genetic analysis because Loh et al. teach using AFLP markers to identify inter and intra-cultivars in *C. bicolors*, an ornamental asexual plant, like that of Poinsettia cultivars, to determine their diversity to provide a reliable and reproducible means of fingerprinting the many *Caladium* cultivars available commercially and for newly developed cultivars (page 155, 2nd column, 1st paragraph).

13. Claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al. (*HortScience*, 1997) in view of Barcaccia et al. (*Journal of Horticultural Science and Biotechnology*, 1999 74(2): 243-50), as defined by Dice (*Ecology*, 1945). It is noted that this rejection was previously presented in section 10 of the office action mailed 08/10/2005 and is applied to newly added claims 70-74 and reiterated below.

Ling et al. teaches a method of distinguishing genetic relationships and diversity between Poinsettia cultivars, including breeding family 'Freedom' (instant claim 5). The method utilizes RAPD analysis to distinguish the identities between Poinsettia cultivars in order to "alleviate some of the confusion of cultivar identity associated with morphological characteristics and multiple cultivar registrations" (p. 124, 1st-2nd column). Figure 3 displays the amplified restriction fragments generated by RAPD analysis and figure 1 demonstrates the cultivar relationships (cultivar linked amplified polymorphism restriction fragments) (claims 71-74). The collection of RAPD data, or database as require in claim 28, enables the computation of the displayed cultivar relationships both in Figure 1 and 2. Ling et al. teach that the RAPD markers can be used for identification of poinsettia cultivars and that the results indicate that RAPD can be used to determine the genetic relationships among cultivars and to estimate genetic diversity between cultivars (page 124, 1st full paragraph). Ling et al. does not teach the AFLP method steps to distinguish genetic relationship or diversity.

Barcaccia et al. teach a method using an AFLP marker protocol to distinguish genetic relationships and diversity of *Pelagorium peltatum*, an ornamental asexual plant. Barcaccia et al. teach using AFLP to generate a fingerprint of each plant (page 245, *AFLP markers*) and determine the identity/diversity by calculating the genetic dissimilarly estimate (GDE) in all pair wise comparisons using the formula by Dice et al (1945) (page 245-6, *Data collection and analysis*) (instant claims 63 and 69). Barcaccia et al. teach digesting genomic DNA with EcoRI and Mse I (page 245, 1st column, 4th full paragraph) (instant claims 7, 24), which have tetranucleotide and hexanucleotide recognition sites (instant claims 6, 23). The genetic dissimilarity of *P. peltatum* is shown in Table III, determining the diversity of the nine plants and

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the recovered flower (page 248) (instant claims 3 and 21). Dice defines the values or scores range from 0 to 1 where 0 indicates dissimilarity and 1 indicates similarity (pp. 298-99, bridging paragraph). Barcaccia teaches all calculations and analyses were conducted on Numerical Taxonomy and Multivariate Analysis System (NTSYS-pc) (page 246, 1st full paragraph, 1st column) (instant claim 30). Barcaccia et al. also teach RAPD marker analysis but teaches that banding patterns were not reproducible in subsequent replicated PCR experiments and therefore, not useable in molecular comparison with the plants (page 247, 2nd column, 1st full paragraph). Further, Barcaccia et al. teach using AFLP revealed consistent diversity between the flower recovered and each of nine DNA samples (page 247, 2nd column, last paragraph). Barcaccia et al. teach that AFLP fingerprinting combines the reliability of RFLP assay with efficiency of the PCR technique and AFLP markers proved to be much more powerful and reliable tool capable of probing a large number of genomic loci per experiment and decimating genetic differences, even between phenotypically similar individuals (page 249, 2nd column, 1st full paragraph). Barcaccia et al. teach using AFLP markers to identify cultivars unambiguously and definitively and are effective for calculating the genetic distance between cultivars (page 249, 2nd column, 3rd full paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the method of identifying poinsettia cultivars by RAPDs marker taught by Ling et al. to include the AFLP marker assay as taught by Barcaccia et al. One of ordinary skill in the art would have been motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Barcacci et al. because Barcacci et al. teaches of the advantages of using the AFLP procedure to analyze genetic relationships and

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diversity in ornamental plants in order to obtain reproducible, reliable, efficient results. Further, Barcacci et al. motivates the ordinary artisan to use the AFLP technique because Barcacci et al. teaches that using AFLP fingerprinting combines the reliability of RFLP assay with efficiency of the PCR technique and AFLP markers proved to be much more powerful and reliable tool capable of probing a large number of genomic loci per experiment and discriminating genetic differences, even between phenotypically similar individuals (page 249, 2nd column, 1st full paragraph). The ordinary artisan would have had a reasonable expectation of success in using AFLP marker assay taught by Barcaccia in the method taught by Ling et al. of Poinsettia cultivar genetic analysis because Barcaccia et al. teach using AFLP markers to identify cultivars unambiguously and definitively and teaches that AFLP markers have the ability to identify new cultivars to determine their diversity with respect to previously registered cultivars of decorative plants (ornamental plants) (page 249, 2nd column 3rd full paragraph).

14. The rejection of claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69-74 under 35 USC §103(a) as being unpatentable over Ling et al. (*HortScience*, 1997) in view of Sukhwinder et al. (*Crop Improvement*, 1998), as defined by Dice (*Ecology*, 1945) in section 18, pages 6-8 of the previous office action, is applied to newly added claims 70-74 and reiterated below.

Ling et al. teaches a method of distinguishing genetic relationships and diversity between Poinsettia cultivars, including breeding family 'Freedom' (claim 5). The method utilizes RAPD analysis to distinguish the identities between Poinsettia cultivars in order to "alleviate some of the confusion of cultivar identity associated with morphological characteristics and multiple cultivar registrations" (p. 124, 1st-2nd column). Figure 3 displays the amplified restriction

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fragments generated by RAPD analysis (cultivar-linked amplified polymorphic restriction fragments, claims 70-74) and figure 1 (and legend) demonstrates the computed cultivar relationships. The collection of RAPD data, or database as required in claim 28, enables the computation of the displayed cultivar relationships both in Figure 1 and 2.

Ling et al. does not teach the AFLP method steps of distinguishing genetic relationship or diversity as required by the claims.

Sukhwinder et al. teaches a method of distinguishing genetic relationships and diversity between *Oryza* cultivars (rice) utilizing AFLP analysis. In using the AFLP assay, the pattern of a collection of amplified restriction fragments of one plant/cultivar (its fingerprint) is compared to another in order to determine its similarity or dissimilarity to known cultivars (p. 17, figure 1) as required by claim 1. The fragments are generated utilizing restriction enzymes MseI and EcoRI (p. 16, 2nd column, 1st paragraph)(claims 7, 24), which have tetranucleotide and hexanucleotide recognition sites (claims 6, 23). The comparison is based upon a computed similarity coefficient, or 'index value' (claim language) for each comparison to indicate similarity or dissimilarity. The similarity coefficient is taught to be "derived through pair-wise comparison of the genotypes based on the presence or absence of shared polymorphic bands"(p. 18, 1st column, 1st paragraph)(claims 63, 69). Figure 2 demonstrates the Dice coefficient of similarity (claims 3, 21) amongst multiple rice varieties. [Dice defines the values or scores range from 0 to 1, wherein 0 indicates dissimilarity and 1 indicates similarity (pp. 298-299, bridging paragraph)]. A computer program was utilized to generate the dendrogram of figure 2, which displays the clustered results of the performed method (p. 18, 1st column, 1st paragraph) (claim 30). Sukhwinder et al. teaches that other fingerprinting methods such as restriction fragment length

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(RFLP) analysis and random amplified polymorphic DNA (RAPD) assays had been commonly used to discriminate various cultivars, however the new technique of using AFLP “combines reliability and robustness of RFLP and strength of PCR techniques. Sukhwinder et al. teaches that the AFLP technique is considered powerful for genome mapping, genotype identification and phylogenetic studies” (p. 15, 2nd column, 1st paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the Poinsettia cultivar genetic analysis method of Ling et al. and further modify the RAPD procedure used by Ling et al. to the improved method of cultivar analysis using AFLP techniques as per the teachings of Sukhwinder et al. One of ordinary skill in the art would have been motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Sukhwinder et al. because Sukhwinder et al. teaches of the advantages of using the AFLP procedure of analyzing genetic relationships and diversity as opposed to RAPD and RFLP. In addition, Sukhwinder et al. motivates the ordinary artisan to use the AFLP technique because Sukhwinder et al. teaches that although other fingerprinting methods such as RFLP and RAPD assays had been commonly used to discriminate various cultivars, the new technique of using AFLP “combines reliability and robustness of RFLP and strength of PCR techniques”. Sukhwinder et al. teaches that the AFLP technique is considered powerful for genome mapping, genotype identification and phylogenetic studies” (p. 15, 2nd column, 1st paragraph).

15. Claims 1, 3, 5-6, 21, 23, 30, 63 and 69-74 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ling et al. (*HortScience*, 1997), in view of Barker et al. (*Genome*, 1999) as defined by Tullos (Offprint from Palm ME and IH Chapela, eds, 1997) in section 19, pages 8-10 of the previous office action, is applied to newly added claims 70-74 and repeated below.

Ling et al. teaches a method of distinguishing genetic relationships and diversity between Poinsettia cultivars. The method utilizes RAPD analysis to distinguish the identities between poinsettia cultivars in order to "alleviate some of the confusion of cultivar identity associated with morphological characteristics and multiple cultivar registrations" (p. 124, 1st-2nd column). Figure 3 displays the amplified restriction fragments generated by RAPD analysis (cultivar-linked amplified polymorphic restriction fragments, claims 70-74) and figure 1 (and legend) demonstrates the computed cultivar relationships. The collection of RAPD data, or database as require in claim 28, enables the computation of the displayed cultivar relationships both in Figure 1 and 2.

Ling et al. does not teach the AFLP method steps of distinguishing genetic relationship or diversity as required by the claims.

Barker et al. teaches a method of distinguishing genetic relationships and diversity between Salix cultivars (willows) utilizing AFLP and RAPD analysis. The comparison of the band patterns generated by the AFLP assay is carried out by the computation of a similarity coefficient, or 'index value' (claim language) for each comparison to indicate similarity or dissimilarity between plants. The similarity index values were generated utilizing the Jaccard coefficient (claims 3, 21) based upon the combined data set for total bands in addition to

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polymorphic bands that were present or absent generated by restriction digests (p. 178, 1st-2nd column)(claim 1). [Tulloss defines the similarities indices such as the Jaccard coefficient has lower and upper bounds wherein the range is from 0 to 1, wherein 0 indicates dissimilarity and 1 indicates similarity (pp. 126 and 129)]. The bands are fragments generated from the restriction enzymes MseI and PstI, which have tetranucleotide and hexanucleotide recognition sites (p. 176, 1st column, 2nd paragraph)(claims 6, 23). A computer program was utilized to generate the dendograms and plots of figures 2 and 3, which displays the clustered results of the performed method (pp. 179-180) (claim 30). In contrast to the problematic results of RAPD analysis, AFLP was demonstrated to be “highly reproducible and highly discriminatory” (p. 178, 2nd column, 2nd paragraph) therefore Baker et al. suggests that although both assays were informative, the AFLP assay “revealed more genetic diversity and discriminated between closely related clones” (p. 182, 1st column, 2nd paragraph).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention was made to improve the Poinsettia cultivar genetic analysis method of Ling et al. and further modify the RAPD procedure of Ling et al. to the improved method of cultivar analysis using AFLP techniques as per the teachings of Barker et al. One of ordinary skill in the art would have been motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Barker et al. because Barker et al. teaches the advantages of the AFLP method of analyzing genetic relationships and diversity as opposed to RAPD. Barker et al. motivates the ordinary artisan to preferably use AFLP instead of RAPD in determining accurate cultivar identity by demonstrating that although both were informative, the

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AFLP assay “revealed more genetic diversity and discriminated between closely related clones” (p. 182, 1st column, 2nd paragraph).

Response to Arguments

16. Applicants traverses the rejection on pages 11-24 of the response mailed 05/16/2006. Applicants assert on page 12, 2nd full paragraph, that a prima facie case of obviousness has not been established with regard to the combination of the presently cited references Ling et al, in view of Loh et al, Barcaccia et al, Sukhwinder et al, or Barker et al as defined by Dice or Tulloss. The response asserts that no clear and particular evidence has been presented from the prior art that provides any motivation to combine and no evidence has been presented that would have any reasonable expectation of success and thus the outstanding rejection fail to satisfy the Office’s burden necessary to maintain an obviousness rejection. This response has been reviewed and not found persuasive. In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988) and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would be obvious to combine the references because Ling et al. teach a method of determining the genetic relationship among cultivars of poinsettia by the use of RAPD markers for identification of poinsettia cultivars and Ling et al. teach that the results indicate that RAPD can be used to determine the genetic relationships

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among cultivars and to estimate genetic diversity between cultivars (page 124, 1st full paragraph). Each of the references Barcaccia, Sukhwinder, and Barker provide motivation to combine and expectation of succession that the method of RAPD taught by Ling et al. could be modified to include the AFLP method taught by Barcaccia, Sukhwinder, and Barker. For example, Barcaccia et al. teach using AFLP revealed consistent diversity between the unknown flower recovered and each of nine DNA samples (page 247, 2nd column, last paragraph). Barcaccia et al. teach that AFLP fingerprinting combines the reliability of RFLP assay with efficiency of the PCR technique and AFLP markers proved to be much more powerful and reliable tool capable of probing a large number of genomic loci per experiment and decimating genetic differences, even between phenotypic ally similar individuals (page 249, 2nd column, 1st full paragraph). Barcaccia et al. teach using AFLP markers to identify cultivars unambiguously and definitively and are effective for calculating the genetic distance between cultivars (page 249, 2nd column, 3rd full paragraph). Therefore, one of ordinary skill in the art would be motivated to improve the method of genetic analysis used in Ling et al. from RAPD to the AFLP procedure taught by Barcaccia et al. because Barcaccia et al. teaches of the advantages of using the AFLP procedure to analyze genetic relationships and diversity in ornamental plants in order to obtain reproducible, reliable, efficient results. Furthermore, Barcaccia et al. teach that pelargoniums are genetically uniform but to an increasing extent are commercial hybrids with more than 4000 cultivars created by controlled mating or mutations (see page 243, 2nd column, 1st full paragraph). Therefore, one of skill in the art would be motivated to use the method of Barcaccia to identify genetic profiles of poinsettia plants as poinsettia plants are commercial hybrids with many cultivars that have been controlled by mating or mutations and are genetically

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uniform. Furthermore, Sukhwinder et al. teaches that although other fingerprinting methods such as RFLP and RAPD assays had been commonly used to discriminate *various* cultivars, the new technique of using AFLP “combines reliability and robustness of RFLP and strength of PCR techniques”. Additionally, Barker et al. teach the AFLP assay “revealed more genetic diversity and discriminated between closely related clones” (p. 182, 1st column, 2nd paragraph) and therefore the ordinary artisan would have been motivated to use the assay of AFLP to determine genetic variation in poinsettias. Therefore, Barcaccia, Sukhwinder, and Barker teach that an ordinary artisan would have been motivated to use the assay of AFLP to determine genetic variation in poinsettias and teach an reasonable expectation of success that AFLP could be used in the method taught by Ling et al.

The response asserts on pages 12-13 that poinsettias are far removed from the cited references and the taxonomic relationships of the plants, poinsettias, willow, rice, Pelargonium, and Caladium are divergent. The response asserts that one of skill in the art would be well aware that the distant relationship between poinsettias and the references plants and the references of Barker, Sukhwinder, Loh and Barcaccia do no suggest application of AFLP analysis to poinsettia. The response asserts that none of these references teach or suggest that their findings could be applied to other plants. This response has been thoroughly reviewed but not found persuasive. The claimed method is analysis of genetic diversity among poinsettia's which encompasses assaying for mutations in the genome. AFLP, as taught by Barker, Sukhwinder, Loh, and Barcaccia, allows for detection of mutations in the whole genome by AFLP markers which, as taught by Barcaccia proved to be much more powerful and reliable tool capable of probing a large number of genomic loci per experiment and decimating genetic differences, even

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between phenotypic ally similar individuals, and Sukwinder et al. teach that the new technique of AFLP combines reliability and robustness. One of ordinary skill in the art would have been motivated to combine the method of Ling et al. to include the method of AFLP, as taught by Barcaccia, Sukwinder, Loh and Barker because each of these references teach that AFLP is a reliable, powerful technique capable of analyzing mutations within a genome. Furthermore, Barcaccia compares RAPD to AFLP and teaches that the number of AFLP markers generated is much larger than the number of RAPD markers (568 AFLPs markers were generated versus 162 RAPD markers) which would motivate the ordinary artisan to use AFLP in the method of Ling et al. to generate more markers for poinsettias.

17. Applicants traverses the rejection of Ling in view of Loh as further defined by Dice on pages 13-18 of the response. The response assert that there is no suggestion or motivation to apply AFLP analysis to poinsettia and assert that Loh et al. is solely concerned with Caladium and the applicability of AFLP to Caladium cultivars and assert that Caladium is completely unrelated to poinsettia. This response has been thoroughly reviewed but found persuasive. Loh et al. teach studying intra and inter specific variation of Caladium cultivars and Loh et al. teach that AFLP markers are useful in differentiating and characterizing cultivars within a Caladium species, as well as consistency between closely related taxa of Caladium. The ordinary artisan would have been motivated to use AFLP as taught by Loh et al. in the method of Ling et al. to provide a sensitive, reliable, and consistent molecular technique for studying intra- and inter-specific variations of poinsettia (see page 155, 2nd column, 1st paragraph of Loh et la.)

The response asserts on page 15, last paragraph, that the Caladium are developed by hybridization and not by asexual reproduction and point to page 155, first paragraph of Loh et al.

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This response has been thoroughly reviewed but not found persuasive. Loh et al. teach that the majority of *Caladium* are propagated asexually and that new cultivars are developed by hybridization (see page 155, 1st column, 1st paragraph) and assert that breeding by hybridization has much greater genetic diversity than by asexual reproduction. Loh et al. teach a method of identifying particular *C. bicolor* cultivars as well as identifying new cultivars (see abstract) and therefore not all of the plants that were assayed by Loh et al. were propagated by hybridization and the genetic diversity of *C. bicolor* is narrow, as taught by Loh et al. (see figure 4) .

The response asserts on page 16-17 that there were some studies that AFLP analysis in ornamental plants and it was uncertain that there would be sufficient inter-cultivar diversity among poinsettia's that would be detectable by AFLPs and one of ordinary skill in the art could not have had any reasonable expectation of success that sufficient polymorphisms detectable by AFLP would exist among poinsettia cultivars. This response has been thoroughly reviewed but not found persuasive. In response to applicants argument that there was no reasonable expectation of success that sufficient polymorphisms would be detectable by AFLP, several articles, reveal that AFLP was capable of detecting very similar genomic variations at the time the application was filed. For example, Keim et al. (J. Applied Microbiology, 199, 87:215-217) teach use of AFLP for determining molecular diversity in *Bacillus anthracis*. Keim et al. teach that molecular diversity of *B. anthracis* has been difficult to identify (see page 215, 2nd column, 1st paragraph). Keim et al. teach that there were two limitation to molecular diversity studies – lack of diverse strain collection and screening methods did not have sufficient capacity to identify the rare variable genomic location (see page 216, 1st column, 1st paragraph). Keim et al. teach that AFLP identified 30 variable regions which gave the ability to screen a large number of

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potentially diverse strains across a relatively large percentage of *B. anthracis* genome and teach molecular typing of *B. anthracis* by AFLP (see figure 1). Furthermore, Arnold et al. (J Clin Micro. 1999 37:1274-1279) evaluated the potential of AFLP as an epidemiological typing collection with valid phylogenetic basis by applying 87 strains of *E. coli* to AFLP. Arnold et al. teach that AFLP is suitable for providing well defined and reproducible identified or genotypes for each strain of *E. coli* (see abstract). Arnold et al. teach a very similar genetic diversity of *E. coli* obtained by AFLP (see figure 2). Arnold et al. teach that AFLP is suitable for genotyping of strains of *E. coli* (see page 1278, 1st column, 2nd full paragraph). Therefore, at the time the invention was filed it was known in the art that AFLP could distinguish different genomic diversity among very similar genomes, as demonstrated for *E. coli* and *B. anthracis*.

The response asserts that the lack of expectation of success was emphasized by Dr. Moyer's research using SSR analysis with poinsettia and presented in the previous declaration, submitted 5/23/2005 in which the SSR analysis failed to differentiate poinsettia cultivars. The response asserts that SSR analysis would have a reasonable expectation of success in poinsettia but as shown by Dr Moyer's data the SSR analysis failed. This response has been thoroughly reviewed but found persuasive. First, the claims are not drawn to analysis of poinsettia's by SSR but by AFLP analysis and SSR analysis is a different technique than AFLP and can not be used as an indicator for the unpredictability of AFLP in poinsettias. Furthermore, SSR analysis is not as sensitive a technique as AFLP. SSR analysis depends on repeats in the genome and the length of repeats whereas AFLP depends on mutations present in genomic DNA.

The response asserts that the unpredictability is further supported by Mitchell et al. which states the main question we addressed was can Magnolia cultivars be distinguished using AFLP

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markers? and assert that this statement clearly illustrated the uncertainty concerning AFLP on distinguishing cultivars. This response has been thoroughly reviewed but not found persuasive. Mitchell et al. teach that AFLP was used successfully to distinguish cultivars, which is further evidence that AFLP is not unpredictable in distinguishing cultivar, genetic diversity of organisms, as repeated argued by applicant.

The response asserts that the combination of Ling et al., Loh et al, and Dice would have been an obvious to try to apply AFLPs to poinsettia cultivars. This response has been thoroughly reviewed but not found persuasive. Ling et al. describe a detailed enabling methodology of distinguishing genetic relationships and diversity between Poinsettia cultivars, including breeding family 'Freedom' (instant claim 5). The method utilizes RAPD analysis to distinguish the identities between Poinsettia cultivars in order to "alleviate some of the confusion of cultivar identity associated with morphological characteristics and multiple cultivar registrations" (p. 124, 1st-2nd column), however Ling et al. does not teach the AFLP method steps to distinguish genetic relationship or diversity. Loh et al. teach the successful use of AFLP to distinguish genetic relationships between *C. schomburgkii* and *C. bicolor* cultivars and between closely related taxa of *Caladium* (page 161, 1st column, 2nd full paragraph). Loh et al. et al. teach using AFLP markers is useful in differentiating and characterizing cultivars within a *Caladium* species (page 161, 1st column, last paragraph). Loh et al. suggest that AFLP could be used in the method of Ling et al because Loh et al. teaches of the advantages of using the AFLP procedure to analyze genetic relationships and diversity in ornamental plants in order to obtain reproducible and reliable results. Therefore, one of ordinary skill in the art would have been motivated to modify the teachings of Ling to include AFLP as taught Loh et al. The ordinary artisan would

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have had a reasonable expectation of success that AFLP could be used in the method by Ling et al. because Loh et al. teach the use of AFLP to analyze genetic relationships in ornamental plants.

18. Applicants traverse the rejection of Ling et al. in view of Barcaccia as defined by Dice on page 18-22 of the action mailed 05/16/2006. Applicants assert on page 18, that there is no suggestion in the cited Barcaccia et al. publication that AFLP analysis can be applied to poinsettia or suitable for the study of ornamental plants and Barcaccia et al. is solely concerned with geraniums and the applicability of AFLPs to geranium cultivars. Applicants assert that germanium is taxonomically unrelated to poinsettia's and one of ordinary skill in the art would have recognized the enormous difference between geranium and poinsettia's and not found the application of AFLP to geranium to teach suggest or motivate one to apply AFLP. This response has been thoroughly reviewed and not found persuasive. Barcaccia was not cited for its relationship to poinsettia's. Barcaccia was cited because Barcaccia et al. teach that AFLP fingerprinting combines the reliability of RFLP assay with efficiency of the PCR technique and AFLP markers proved to be much more powerful and reliable tool capable of probing a large number of genomic loci per experiment and decimating genetic differences, even between phenotypic ally similar individuals (page 249, 2nd column, 1st full paragraph). Barcaccia et al. teach using AFLP markers to identify cultivars unambiguously and definitively and are effective for calculating the genetic distance between cultivars (page 249, 2nd column, 3rd full paragraph). Therefore, one of ordinary skill in the art would have been motivated to use AFLP, as taught by Barcaccia in the method of Ling et al.

The response asserts that the data in Barcaccia is generated using a small number of geranium plants of unknown genetic origin and assert that there is no evidence that any of these plants represent different cultivars. The response asserts that there is no information on the genetic background of the plants used for the analysis and an ordinary artisan would not have known that AFLP analysis was successful in distinguishing geranium cultivars. This response has been thoroughly reviewed but not found persuasive. It is noted that the claims are drawn to a method of estimating a genetic relationship and the claims do not require that genetic origin of the plant be known. Barcaccia et al. teach that AFLP analysis is successful in identifying genetic relationship between plants and Barcaccia et al. teach that pelargoniums are genetically uniform but to an increasing extent are commercial hybrids with more than 4000 cultivars created by controlled mating or mutations (see page 243, 2nd column, 1st full paragraph) and Barcaccia et al. teaches of the advantages of using the AFLP procedure to analyze genetic relationships and diversity in ornamental plants in order to obtain reproducible, reliable, efficient results.

The response asserts on page 19-20 that the outstanding rejection draws a direct connection between work in germanium and the present invention of poinsettia's. The rejection is based on the premise that there would have been motivation to combine work done in germanium with work done in poinsettia and the use of AFLP in geranium would render obvious the use of AFLP analysis in poinsettia. Applicant assert that their previous argument regarding the distinctness of geranium and poinsettia are direct to the legally deficient foundation of the outstanding rejection that there is no genetic relationship between geranium and poinsettia and there is no motivation to combine the cited references and no reasonable expectation of success. This response has been thoroughly reviewed but found persuasive. As stated previously, neither

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the rejection or the claims are comparing the gene pools of poinsettia and geraniums. The rejection sets forth a prima facie case of obviousness that one of ordinary skill in the art would be motivated to use the technique of AFLP for estimating a genetic relationship between poinsettias because Ling et al. teaches the use of RAPD to distinguish a genetic relationship between poinsettia but does not teach the use AFLP. Barcaccia et al. teach that AFLP analysis is successful in identifying genetic relationship between plants and Barcaccia et al. teaches of the advantages of using the AFLP procedure to analyze genetic relationships and diversity in ornamental plants in order to obtain reproducible, reliable, efficient results. Furthermore, Barcaccia et al. teach that that pelargoniums (geraniums) are genetically uniform but to an increasing extent are commercial hybrids with more than 4000 cultivars created by controlled mating or mutations (see page 243, 2nd column, 1st full paragraph) and therefore teaches that AFLP can determine polymorphic variations and one of ordinary skill in the art would be motivated to use AFLP to detect polymorphic variations. If a polymorphic variation existed, one would expect that AFLP would detect the variation successfully, as taught by Barcaccia et al, Sukhwinder et al, and Barker et al. for many different types of plants (rice, geraniums, willow). The response repeatedly uses the argument that the genetic relationship between poinsettias and rice, geraniums, willows, etc. is distinct, however none of the rejections or the claims require distinguishing the genetic relationship between poinsettia's or other species or require that the genetic relationship be the same. The rejections of record establish that it would be obvious to use AFLP in the method of distinguishing a genetic relationship between poinsettia as taught by Ling et al.

The response asserts that they wish to clarify their previous argument so that the examiner can reconsider the Moyer declaration submitted 05/23/2005. The response asserts that SSR analysis is generally considered to be very powerful and one would assume that SSR analysis to determine genetic relationships would be obvious but SSR was not able to reliably detect genetic relationships in poinsettia. Applicant assert again that one must detect the “right” markers and that it could not be obvious to one of ordinary skill in the art at the time of invention that AFLP would detect the “right” markers. This response has been thoroughly reviewed but not found persuasive. First, the claims are not drawn to the “right” markers. The claims are drawn to a method of estimating a genetic relationship between a genomic DNA and a cultivar, as repeatedly shown in several references, Loh, Barcaccia, Barker, as well as Arnold et al. and Keim et al. that AFLP can distinguish genetic relationship, even within very similar species (*E. Coli* and *B. anthracis*) and there is no evidence that AFLP would not have worked for poinsettias. As stated in the previous office action, with regard to Moyer’s declaration, as the claims are not limited to the use of SSR or microsatellites to evaluate the genetic relationships among poinsettias nor are the claims are drawn to a method of identifying poinsettia’s by using SSR or microsatellites. The claims are drawn to method of identifying poinsettias by AFLP. The claims simply require some level of polymorphic analysis using AFLP which is obvious over Ling et al, Barcaccia et al. and Dice.

The response asserts that Barcaccia did not evaluate the breeding history of the plant because breeding history of the plant refers to methods that provide information regarding the pedigree of the plant. This response has been reviewed but not found persuasive as the claims do not require the pedigree of the plant. Furthermore, Barcaccia et al. teach using AFLP to generate

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a fingerprint of each plant (page 245, *AFLP markers*) and determine the identity/diversity by calculating the genetic dissimilarity estimate (GDE) in all pair wise comparisons using the formula by Dice et al (1945) (page 245-6, *Data collection and analysis*). Furthermore, Barcaccia et al. teach using AFLP markers to identify the genetic relationship (identity vs. diversity) (breeding history) between a found flower and another plant (see page 244, 1st column, 2nd full paragraph). Therefore, Barcaccia et al. teach using AFLP markers to identify the breeding history of a plant (the found flower to a known plant). Therefore, Barcaccia et al. teach using AFLP markers to evaluate the breeding history of an asexual plant.

19. The response traverses the rejection of Ling et al. in view of Sukhwinder et al. as defined by Dice on page 22-23. The response asserts that the AFLP work in rice by Sukhwinder is not relevant to poinsettia and would not have provided motivation to combine or reasonably expect success with respect to the claimed invention. The response asserts that the use of AFLP in rice is distinct from its application to poinsettias, asserting that rice is unrelated taxonomically to poinsettias. The response further asserts that there would have been no reasonable expectation for the ordinary skilled worker that one would be able to apply AFLP analysis to determine genetic relationships among poinsettia cultivars. These arguments have been thoroughly reviewed but were not found persuasive. While Sukhwinder et al. does not teach using AFLP to determine genetic relationships for poinsettias cultivars, it would have been obvious to one skilled in the art at the time of the invention to use AFLP method taught by Sukhwinder to determine genetic relationships for poinsettias cultivars because Sukhwinder et al. teaches that although other fingerprinting methods such as RFLP and RAPD assays had been commonly used to discriminate *various* cultivars, the new technique of using AFLP “combines reliability and

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robustness of RFLP and strength of PCR techniques”. Therefore, one of skill in the art would have been motivated to use the method of Sukhwinder et al. with poinsettia cultivars as Sukhwinder et al. suggest that this new technique can discriminate *various* cultivars, which could include poinsettia cultivars.

The response traverses the rejection of Ling et al. in view of Barker as defined by Tulloss. The response asserts again that AFLP in willow work is not relevant to poinsettia’s and would not provide the requisite motivation or expectation of success with respect to the present invention. This argument has been thoroughly reviewed but was not found persuasive because the willow is an asexual plant, like the poinsettia, and the genetic variation, regardless of the origin of DNA, is analyzed and evaluated in the same manner. Barker et al. teach the AFLP assay “revealed more genetic diversity and discriminated between closely related clones” (p. 182, 1st column, 2nd paragraph) and therefore the ordinary artisan would have been motivated to use the assay of AFLP to determine genetic variation in poinsettias

20. The declaration submitted on 5/16/2006 by Moyer does not overcome the rejections of record. The declaration asserts the application of AFLP technology to any particular plant is uncertain and assert that it is relevant to consider how distantly related poinsettia is to rice, willow, Pelargonium and Caladium. The declaration provides a taxonomic relationship of poinsettia’s to each of these plants. The declaration asserts that it is impossible to generalize findings about one member of subclass Rosidae to another. This response has been thoroughly reviewed but not found persuasive. It is noted that each of the references cited that use AFLP technology were cited not to compare the relationship between a poinsettia to the other species but to demonstrate that at the time the invention was made it would have been obvious to use

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AFLP in the method by Ling et al, which establishes a genetic diversity of poinsettia' plants by use of RAPD. The claims do not require any taxonomic relationship and are drawn to a method of estimating a genetic relationship between a genomic DNA and a cultivar, as repeatedly shown in several references, Loh, Barcaccia, Barker, as well as Arnold et al. and Keim et al. that AFLP can distinguish genetic relationship, even within very similar species (E. Coli and B. anthracis) and there is no evidence that AFLP would not have worked for poinsettias. Furthermore, AFLP analyzes the DNA of the species and does not compare the taxonomic relationship of the species. AFLP, as taught by Barker, Sukhwinder, Loh, and Barcaccia, allows for detection of mutations in the whole genome by AFLP markers which, as taught by Barcaccia proved to be much more powerful and reliable tool capable of probing a large number of genomic loci per experiment and decimating genetic differences, even between phenotypic ally similar individuals, and Sukwinder et al. teach that the new technique of AFLP combines reliability and robustness.

The claims simply require some level of polymorphic analysis using AFLP. The diversity among poinsettia taxonomy to other species is not relevant to the rejection of record. The declaration further asserts that a scientist in the field would at most think to try such a technique but would enter into the research without any expectation of success since it is known that poinsettia's have a very narrow genetic basis. As repeatedly stated above, there is an expectation of success that AFLP could be used with poinsettias as taught in the references of Loh, Barcaccia, Barker, and Sukhwinder. Furthermore, as stated above Arnold and Keim et al. teach using AFLP in B. anthracis and E. coli, which both have very narrow genetic basis. Therefore, there is no evidence in the art that would lead an ordinary artisan to believe that AFLP would not work with poinsettias.

For these reasons, and the reasons made of record in the previous office actions, these rejections are maintained.

Conclusion

21. Claims 2, 4, 10, 11, 22, 27-29, 52, and 64 are free of the cited prior art and are objected to for being dependent on rejected claims. The claims would be allowable if rewritten with all claim limitations from claims which they depend.

22. Claims 1, 3, 5-7, 21, 23-24, 30, 63 and 69-74 are not allowable over the cited prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sarae Bausch whose telephone number is (571) 272-2912. The examiner can normally be reached on M-F 10am-7pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

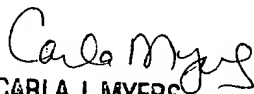
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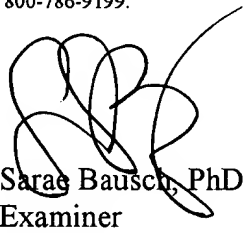
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